

## TEXT OF PROPOSED REGULATIONS

### TITLE 3. CALIFORNIA CODE OF REGULATIONS DIVISION 6. PESTICIDES AND PEST CONTROL OPERATIONS CHAPTER 2. PESTICIDE SUBCHAPTER 1. PESTICIDE REGISTRATION

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Current wording is indicated by regular type.  
Proposed deletions are indicated by ~~strikeout~~.  
Proposed additions are indicated by underline.

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#### ARTICLE 2. REGISTRATION REQUIREMENTS

Amend section 6170(a) and (b) to read:

##### **6170. Application.**

(a) Each application for registration of a pesticide product<sup>1</sup> shall be made on the Application for Pesticide Registration Form 39-030 (Rev. 9/03) prescribed by the director and described in section 6170.5. The application is incomplete and may be returned by the Director if the application is not accompanied by the fee required by section 6148, six copies of the product labeling, and the data required to be submitted by sections 6159, 6170, 6172, 6176-6179, 6180(a), 6181-6192,<sup>1</sup> and 6200 when applicable to support registration of the product. All data submitted by the applicant<sup>1</sup> to the U.S.<sup>1</sup> EPA in support of federal registration of the product<sup>1</sup> shall be submitted in full. The product labeling should be printer's proof, final labels or legible photocopies, thereof. If typescript labels are submitted with the application, printer's proof, final labels or legible photocopies, thereof, must be submitted before a Certificate of Registration (License) for the product will be issued. If the label has been approved by a federal agency, proof of such approval shall be submitted with the application.

(b) An application to amend the labeling (including a special local needs labeling) of a pesticide product<sup>1</sup> is incomplete and may be returned by the Director if the application is not accompanied by the fee required by section 6148.5, six copies of the labeling and the data required to be submitted by sections 6159, 6170, 6172, 6176-6179, 6180(a), 6181-6192, and 6200 when applicable to the amendment. The application to amend the labeling shall be accompanied by all data submitted by the applicant<sup>1</sup> to the U.S.<sup>1</sup> EPA in support of the federal amended labeling of the product<sup>1</sup> and all studies shall be submitted in full. The product labeling should be printer's proof, final labels or legible photocopies, thereof. If typescript labels are submitted, printer's proof, final labels or legible photocopies, thereof, must be submitted before the amended label will be accepted for use. If the amended labeling has been approved by a federal agency, proof of such approval shall be submitted with the amendment application.

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NOTE: Authority cited: Section 12781, Food and Agricultural Code.

Reference: Sections 12811, 12812, 12815 and 12816, Food and Agricultural Code.

Amend section 6172(a) to read:

**6172. General Toxicity Data.**

(a) The following data shall be submitted with every application for registration.

(1) Acute oral and dermal LD50 data on the product ~~and active ingredient~~.<sup>1</sup>T

(2) Acute LC50 data on products which produce a respirable aerosol or gas

(3) Primary eye and skin irritation data on the product ~~and active ingredient~~.<sup>1</sup>

(b) The following data in addition to the data required by (a), (1)-(3), shall be submitted with each application to register a product containing an active ingredient not previously registered when required by the U.S. EPA to support the full unconditional registration pursuant to Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act. Pesticides which are determined to be biorational pesticides as determined by the director, may be exempted from the chronic toxicity data requirements.

(1) Results of a two-year feeding study for oncogenicity on active ingredients in two animal species.

(2) Results of a teratogenicity study and a two-generation combined male-female reproductive study on active ingredients.

(3) Results of three mutagenicity studies on active ingredients that detect gene mutations, chromosomal aberrations, and DNA damage/repair.

Note: Authority cited: Sections 12781 and 12824, Food and Agriculture Code

Reference: Sections 11501 and 12824-12825, Food and Agricultural Code.

Amend section 6200(c) to read:

**6200. Conditional Registration.**

The director may waive specific data requirements in this subchapter for a period reasonably sufficient, not to exceed three years, for the generation and submission of such required data provided:

(a) The pesticide product is registered pursuant to the Federal Insecticide, Fungicide and Rodenticide Act, the product is to be used under a Federal Experimental Use Permit, or the product is for use in California only.

(b) The applicant has provided the director with all data the applicant has available required by the U.S. EPA and by this subchapter to support registration of the pesticide product.

(c) No conditional registration shall be granted unless the data includes all of the following:

(1) Acute oral and dermal LD50 data on the product ~~and active ingredient~~.<sup>1</sup>

(2) Acute LC50 data on products which produce respirable aerosols or gases.

(3) Primary eye and skin irritation data on the product ~~and active ingredient~~.<sup>1</sup>

(4) When human contact is likely with soils or foliage containing residues, foliar and soil residue data as specified in Sections 6181 and 6182, sufficient to establish safe reentry level or interval.

(5) Analytical methods to determine residues of (1) each active ingredient and (2) each toxic metabolite that may result from the active ingredient for which a tolerance has been established by the U.S. EPA in the Code of the Federal Regulations. Test methods shall, as applicable, allow the director to determine residues in or on plant tissue, soil, and water.

- (6) Preliminary efficacy data indicating the product is effective for the proposed use.
- (d) The director complies with Section 6158.

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NOTE: Authority cited: Sections 11456 and 12781, Food and Agricultural Code.

Reference: Sections 11501 and 12824-12825, Food and Agricultural Code.

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<sup>1</sup> The Office of Administrative Law (OAL) initially approved these proposed changes on June 5, 2002 (OAL File No. 02-0423-03N) and August 14, 2002 (OAL File No. 02-0729-01N), respectively, as changes without regulatory effect. However, a recent Appellate Court ruling (*Syngenta Crop Protection, Inc. v. Helliker* [2006] 136 Cal.App.4th 1464) found the changes to be substantive and ruled that even though these amendments were consistent with DPR's practice under the former regulations, DPR was required to inform the public of the proposed amendments.

The text in the existing 3 CCR reflects the language that was approved on June 5 and August 14, 2002, and will not be revised until judgment becomes final. However, DPR is proceeding to adopt these proposed amendments under the rulemaking procedures of Chapter 3.5, Article 5 of the APA. Therefore, the text of the proposed regulations does not reflect what is currently published in 3 CCR. The proposed regulations are presented as if the additions and deletions are being made to the text that existed prior to the changes made in 2002.